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SCHWEGMAN, LUNDBERG & WOESSNER, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER	
SMITH, TERRI L	
ART UNIT	PAPER NUMBER
3762	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/667,206	TERNES, DAVID	
	Examiner	Art Unit	
	Terri L. Smith	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38-45 and 49-80* is/are rejected.

7)☒ Claim(s) *46-48* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12-26-06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed on 26 December 2006 with respect to claims 38–80 have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment.

2. Regarding Applicant's request that the Examiner cite one or more references in support of the positions taken with respect to: claims 53, 54 and 69, Examiner cites Tsuda, U.S. Patent 5,980,464; claims 66 and 67 Examiner cites Bernard et al., U.S. Patent 4,883,063; claims 57, 58, 60 and 70, Examiner cites Kroll et al., U.S. Patent 7,162,299; claim 59, Examiner cites King et al., U.S. Patent 7,155,278; claims 60 and 70, Examiner cites Norris et al., U.S. Patent 6,823,213; claim 61, Examiner cites Levine et al., U.S. Patent 6,973,350; claim 70, Examiner cites the article provided in Applicant's IDS *Cardiac Contractility Sensor Evaluation in a DDDR System – A Multicenter Study*, Progress in Biomedical Research, June 1998.

3. Additionally, Examiner has included the Dardik, U.S. Patent 5,163,439 reference on the Notice of References Cited form as requested by Applicant. The reference was inadvertently left off of said form included with the Office Action mailed on 19 September 2006.

Information Disclosure Statement

4. The information disclosure statement filed on 26 December 2006 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the incorrect date is listed for USP Document Number 5,669,391 and the dates listed on the lined out non-patent literature do not match those present on the documents provided. It has been placed in the application file, but the information referred to herein has not been considered as to the merits. Applicant is advised

that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 38, 40, 41, 42, 50–56, 62, 64, 65, 68, 69, 71, 72, 74, 75 and 76 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsuda, U.S. Patent 5,980,464.

7. Regarding clams 38, 69, 71 and 72, Tsuda discloses a processor circuit (e.g., FIG. 1, element 28), including at least one predetermined criteria (e.g., column 19, lines 54–55) to automatically identify a beginning and an end of an exercise episode of a patient (e.g., FIGS. 8–11; column 19, lines 55–65), and including a data input circuit to receive data associated with an episode (e.g., element 60);

a memory storage circuit, coupled to a data input circuit to store data (e.g., elements 32 and 34); and

an external display (e.g., FIG., 1, element 36; FIG. 9, element 37), including a displayed summary of an episode (FIG. 9), a summary including at least one displayed prognostic indicator obtained from data associated with an episode (e.g., FIG. 9, element 120).

8. With respect to claims 40, 41, 50, 74 and 75, Tsuda discloses a data input circuit receives heart rate/activity sensor data (e.g., elements 10-cuff and 38-pressure pulse wave sensor; FIG. 4; column 10, line 65–column 11, line 26; column 24, lines 43–45), and one at least one heart rate/activity sensor threshold that defines an episode for activity sensor levels that substantially continuously exceed an activity sensor threshold (e.g.,

9. Regarding claims 42 and 76, Tsuda discloses at least one user-provided trigger identifying an episode (e.g., FIG. 1, element 65-pedal).

10. With respect to claims 50–56, Tsuda discloses an indication of a maximum heart rate obtained … (claim 50); an indication of an age-predicted maximum heart rate … (claim 51); an indication of a comparison between a maximum heart rate and of a age-predicted maximum heart rate … (claim 52); a resting heart rate (claim 53); an elevated value of a resting heart rate (claim 54); a heart rate variability (claim 55); and a low heart rate variability (claim 56) (e.g., FIGS. 4 and 7; column 10, lines 22–44; column 15, lines 31–56).

11. Regarding claims 62, 64, 65 and 68, in FIG. 5, Tsuda discloses a displayed graph of heart rate vs. time (claim 62) and patient activity vs. time (claim 68) (e.g., FIG. 5); an indication of an age-predicted maximum heart rate (claim 64) (e.g., element 90) ; and one exercise period during an episode (claim 65) (e.g., element 106).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 43, 44, 45, 63, 77, 78 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsuda, U.S. Patent 5,980,464 as applied to claims 38 and 72 above, and in view of Gamlyn et al., U.S. Patent 5,749,367.

14. Regarding claims 43 and 77, Tsuda discloses the essential features of the claimed invention as described above except for an indication of how many ectopic beats occurred during an episode. However, the device of Gamlyn et al., which is used in patients undergoing exercise (e.g., column 1, lines 15–17) and which automatically monitors changes in heart condition (e.g., column 1, lines 27–29), disclose an indication of how many ectopic beats occurred during an episode (e.g., FIG. 22B; column 3, lines 18–22 and 40–43) to yield the predictable results of facilitating the removal of distinctive irregular heart beats to increase signal accuracy and reduce false identifications of signals.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Tsuda to include an indication of how many ectopic beats occurred during an episode, as taught by Gamlyn et al. because it is an acceptable practice to use a known technique to improve similar devices in the same way to yield the predictable results, in the instant case, of facilitating the removal of distinctive irregular heart beats to increase signal accuracy and reduce false identifications of signals.

15. With respect to claims 44, 45, 63, 78 and 79, Tsuda and Gamlyn et al. disclose the essential features of the claimed invention as described above except for an indication of how many ectopic beats occurred during an exercise portion (claims 44 and 78) and during a post-exercise recovery portion (claims 45 and 79); and an ectopic beat indicator associated with each ectopic beat occurring during an episode (claim 63). However, it is well known in the art to

include an indication of how many ectopic beats occurred during an exercise portion and during a post-exercise and an ectopic beat indicator associated with each ectopic beat occurring during an episode recovery portion to yield the predictable results of assisting health care providers in deciding which patients need invasive testing, aggressive treatment and close monitoring.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Tsuda and Gamlyn et al. to include an indication of how many ectopic beats occurred during an exercise portion and during a post-exercise recovery portion and an ectopic beat indicator associated with each ectopic beat occurring during an episode because applying a known technique to a known device ready for improvement to yield predictable results such as, in the instant case, assisting health care providers in deciding which patients need invasive testing, aggressive treatment and close monitoring, is an acceptable practice.

16. Claims 39, 49, 57–61, 66, 67, 70, 73 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsuda, U.S. Patent 5,980,464.

17. Regarding claims 39, 49, 66, 73 and 80, Tsuda discloses the essential features of the claimed invention as described above except for an episode includes a post-exercise recovery period (claims 39 and 73) and an indication of a rate of decrease of a patient's heart during a post-exercise recovery portion (claims 49 and 80) and a second indicator of at least one post-exercise refractory period during an episode (claim 66). However, it is well known in the art for an episode to include a post-exercise recovery period and to include an indication of a rate of decrease of a patient's heart during a post-exercise recovery portion and to include a second

indicator of at least one post-exercise refractory period during an episode to yield the predictable result of effectively monitoring and evaluating the condition of a patient's heart to determine the overall condition of the patient and subsequently make competent decisions regarding critical, accurate and safe continued patient treatments and therapies.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Tsuda to include an episode includes a post-exercise recovery period and an indication of a rate of decrease of a patient's heart during a post-exercise recovery portion and a second indicator of at least one post-exercise refractory period during an episode because it is an acceptable practice to apply a known technique to a known device ready for improvement to yield predictable results such as, in the instant case, effectively monitoring and evaluating the condition of a patient's heart to determine the overall condition of the patient and subsequently make competent decisions regarding critical, accurate and safe continued patient treatments and therapies.

18. With respect to claims 57–61, Tsuda discloses the essential features of the claimed invention as described above except for an indication of T-wave alternans (claim 57), a heart rate corresponding to an onset of a T-wave alternans (claim 58), heart rate turbulence associated with an episode (claim 59), QT dispersion (claim 60) and paroxysmal atrial tachyarrhythmia (claim 61) associated with an episode. However, it is well known in the art to include an indication of T-wave alternans, a heart rate corresponding to an onset of a T-wave alternans, heart rate turbulence associated with an episode, QT dispersion and paroxysmal atrial tachyarrhythmia associated with an episode to yield the predictable result of determining the overall condition of a patient and improving a diagnostic value during exercise testing.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Tsuda to include an indication of T-wave alternans, a heart rate corresponding to an onset of a T-wave alternans, heart rate turbulence associated with an episode, QT dispersion and paroxysmal atrial tachyarrhythmia associated with an episode because applying a known technique to a known device ready for improvement to yield predictable results such as, in the instant case, determining the overall condition of a patient and improving a diagnostic value during exercise testing, is an acceptable practice.

19. Regarding claims 67 and 70, Tsuda discloses the essential features of the claimed invention as described above except for first and second indicators include different background colors (claim 67) and a processor is located in an implantable device (claim 70). However, it is well known in the art that first and second indicators include different background colors and a processor is located in an implantable device to yield the predictable results of quickly and accurately reading different data being displayed simultaneously and of effectively monitoring patient heart rate in an unimpeded manner while the patient is exercising in order to accurately assess a patient's overall health condition.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Tsuda to include first and second indicators include different background colors and a processor is located in an implantable device to yield the predictable results of quickly and accurately reading different data being displayed simultaneously and of effectively monitoring patient heart rate in an unimpeded manner while the patient is exercising in order to accurately assess a patient's overall health condition.

Allowable Subject Matter

20. Claims 46–48 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

21. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. *Study: Heart after exercise test can predict death risk*, CNN.com/HEALTH, February 27, 2003, 2 pages teaches an indication of ectopic beats occurring during an exercise and post-exercise recovery portion of an episode. Khavari, U.S. Patent 5,706,822 and Bernard et al., U.S. Patent 4,883,063 and Kunig, U.S. Patent 4,622,980 teach post-exercise recovery portions of an episode.

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this Final Action.

23. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is (571) 272-7146. The Examiner can normally be reached on Monday - Friday between 7:30 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/T. L. S./
Examiner, Art Unit 3762
February 18, 2008
/George R Evanisko/
Primary Examiner, Art Unit 3762